



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	7460.00
True Name	Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D-Mannheimia Haemolytica Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	One Shot Ultra 8 - Nasser Mohamed Nasser Co. One Shot Ultra 8 - No distributor specified One Shot Ultra 8 - Zoetis Argentina One Shot Ultra 8 - Zoetis Colombia S.A.S. One Shot Ultra 8 - Zoetis Hayvan Sagligi Ltd One Shot Ultra 8 - Zoetis Mexico One Shot Ultra 8 - Zoetis Russia
Date of Compilation Summary	July 07, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy
Pertaining to	<i>Clostridium chauvoei</i>
Study Purpose	Demonstrate effectiveness against <i>Clostridium chauvoei</i>
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	<i>Clostridium haemolyticum</i>
Study Purpose	Demonstrate effectiveness against <i>Clostridium haemolyticum</i>
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	<i>Clostridium novyi</i>
Study Purpose	Demonstrate effectiveness against <i>Clostridium novyi</i>
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	<i>Clostridium perfringens</i> Type C
Study Purpose	Demonstrate effectiveness against <i>Clostridium perfringens</i> Type C
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	<i>Clostridium perfringens</i> Type D
Study Purpose	Demonstrate effectiveness against <i>Clostridium perfringens</i> Type D
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	<i>Clostridium septicum</i>
Study Purpose	Demonstrate effectiveness against <i>Clostridium septicum</i>
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	<i>Clostridium sordelli</i>
Study Purpose	Demonstrate effectiveness against <i>Clostridium sordelli</i>
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	<i>Mannheimia haemolytica</i>
Study Purpose	Demonstrates effectiveness against <i>Mannheimia haemolytica</i>
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	June 21, 1991

Study Type	Efficacy
Pertaining to	<i>Mannheimia haemolytica</i>
Study Purpose	Demonstrate effectiveness against <i>Mannheimia haemolytica</i>
Product Administration	
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	August 20, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle under field conditions
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	September 8, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle under field conditions
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	09/08/1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle under field conditions
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	09/08/1999